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EXAMINER	
BRUSCA, J	
ART UNIT	PAPER NUMBER
1805	4

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Please find below a communication from the EXAMINER in charge of this application.

Commissioner of Patents

# Office Action Summary

Application No.  
**08/738,944**

Applicant(s)  
**Peterson et al.**

Examiner  
**John S. Brusca**

Group Art Unit  
**1805**



- ☐ Responsive to communication(s) filed on \_\_\_\_\_.
- ☐ This action is **FINAL**.
- ☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

## Disposition of Claims

- ☒ Claim(s) 1-26 is/are pending in the application.
- Of the above, claim(s) 22-24 is/are withdrawn from consideration.
- ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- ☒ Claim(s) 1-21, 25, and 26 is/are rejected.
- ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- ☐ Claims \_\_\_\_\_ are subject to restriction or election requirement.

## Application Papers

- ☒ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- ☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.
- ☒ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

- ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- ☐ All ☐ Some\* ☐ None of the CERTIFIED copies of the priority documents have been
- ☐ received.
- ☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_.
- ☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

- ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

- ☒ Notice of References Cited, PTO-892
- ☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_
- ☐ Interview Summary, PTO-413
- ☒ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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## DETAILED ACTION

### *Election/Restriction*

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - I. Claim 1-21, 25, and 26, drawn to gene expression libraries and methods of making gene expression libraries, classified in class 536, subclass 23.1.
  - II. Claims 22-24, drawn to cosmid vectors, classified in class 435, subclass 320.1.
2. The inventions are distinct, each from the other because of the following reasons:

Inventions II and I are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the cosmid vectors could be used to clone a single selected gene and the libraries and their method of making could utilize vectors other than cosmids.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

Because these inventions are distinct for the reasons given above and the search required for Group II is not required for Group I, restriction for examination purposes as indicated is proper.

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During a telephone conversation with Chris Tsang on 4/17/97 a provisional election was made with traverse to prosecute the invention of Group I, claims 1-21, 25, and 26. Affirmation of this election must be made by applicant in responding to this Office action. Claims 22-24 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(h).

### *Specification*

3. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the following reasons:

Nucleic acid sequences appear in figures 5A, 5B, 5C, 5D, 5E, 5F, and 10, and on page 85-86 of the specification but applicants have not submitted a Sequence Listing as set forth in 37 CFR § 1.821 (see MPEP § 2422).

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Applicants are required to comply with all of the requirements of 37 CFR § 1.821 through 1.825. Any response to this office action which fails to meet all of these requirements will be considered non-responsive. The nature of the sequences disclosed in the instant application has allowed an examination on the merits, the results of which are communicated below.

*Drawings*

4. The drawings are objected to under 37 CFR 1.83(a) because they fail to show in Figure 5E the second reactant without attached beads as described in the specification. The invention as illustrated in figure 5E will not result in concatemerization of fragments of genomic or cDNA because fragments without attached beads are not indicated. Any structural detail that is essential for a proper understanding of the disclosed invention should be shown in the drawing. MPEP § 608.02(d). Correction is required.

*Claim Rejections - 35 USC § 112*

5. Claims 1-21, 25, and 26 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-12 and 25 are indefinite for recitation of the phrase "a cDNA or genomic DNA fragment derived from a plurality of species of donor organisms" because it is not clear

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whether each construct contains more than one cDNA or genomic fragment, and it is not clear how a construct can contain only one fragment that is derived from a plurality of species. The rejection would be obviated by amending claim 1 to recite --multiple cDNA or genomic DNA fragment derived from a plurality of species of donor organisms --. For the purpose of examination, the claims have been assumed to read on expression constructs containing multiple cDNA or genomic fragments.

Claims 3, 15, 25, and 26 are indefinite because it is not clear, in view of the disclosure, whether the claims are drawn to expression constructs containing only preselected fragments or a combination of preselected and unselected fragments. For the purpose of examination, the claims have been assumed to be drawn to expression constructs containing preselected inserts.

Claims 13-21, and 26 are indefinite because it is not clear whether the claims are drawn to expression constructs containing more than one cDNA or genomic DNA fragment, and it is not clear how an expression construct containing only one cDNA or genomic DNA fragment can contain fragments derived from multiple species of donor organisms. The rejection would be obviated by amending claims 13 and 18 to be clearly drawn to expression constructs with multiple cDNA or genomic DNA fragments. For the purpose of examination, the claims have been assumed to be drawn to expression constructs containing multiple cDNA or genomic fragments.

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Claims 1-21, 25, and 26 are indefinite for recitation of the phrase "capable of". It is not clear if the claims are drawn to a latent property or a property that requires an additional agent for expression. The claims should be amended to distinctly recite the claimed properties using positive language.

Claim 8 is indefinite because it is not clear whether the claimed modified cells are modified before introduction of the expression library or are modified as claimed due to introduction of the expression library.

### ***Double Patenting***

6. The non-statutory double patenting rejection, whether of the obviousness-type or non-obviousness-type, is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent. *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); and *In re Goodman*, 29 USPQ2d 2010 (Fed. Cir. 1993).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(b) and (c) may be used to overcome an actual or provisional rejection based on a non-statutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.78(d).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

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Claims 1-21, 25, and 26 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-5, 7, 11, 13, and 15-22 of copending Application No. 08/639255 in view of Frost et al.

This is a provisional obviousness-type double patenting rejection.

Claims 1-21, 25, and 26 of the instant application are drawn to gene expression libraries comprising mobilizable shuttle vectors linked to multiple cDNA or genomic DNA fragments, and their method of making.

Claims 1-5, 7, 11, 13, and 15-22 of copending Application No. 08/639255 gene expression libraries comprising shuttle vectors linked to multiple cDNA or genomic DNA fragments, and their method of making. Claims 1-5, 7, 11, 13, and 15-22 of copending Application No. 08/639255 are not drawn to mobilizable shuttle vectors.

Frost et al. reviews mobilizable plasmids that can be introduced into host cells by a process of conjugation.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to modify the libraries of copending Application No. 08/639255 by use of mobilizable shuttle vectors because Frost et al. shows that mobilizable vectors may be used to introduce plasmids to host cells by a process of conjugation.

7. Claims 1-21, 25, and 26 are directed to the same invention as that of claims 1-5, 7, 11, 13, and 15-22 of commonly assigned copending Application No. 08/639255. The issue of



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priority under 35 U.S.C. 102(g) and possibly 35 U.S.C. 102(f) of this single invention must be resolved.

Since the Patent and Trademark Office normally will not institute an interference between applications or a patent and an application of common ownership (see MPEP § 2302), the assignee is required to state which entity is the prior inventor of the conflicting subject matter. A terminal disclaimer has no effect in this situation since the basis for refusing more than one patent is priority of invention under 35 U.S.C. 102(f) or (g) and not an extension of monopoly.

Failure to comply with this requirement will result in a holding of abandonment of this application.

***Claim Rejections - 35 USC § 103***

8. Claims 1-21, 25, and 26 are provisionally rejected under 35 U.S.C. 103(a) as being obvious over copending Application No. 08/639255 which has a common inventor with the instant application in view of Frost et al. Based upon the earlier effective U.S. filing date of the copending application, it would constitute prior art under 35 U.S.C. 102(e) if patented. This provisional rejection under 35 U.S.C. 103(a) is based upon a presumption of future patenting of the conflicting application.

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Claims 1-21, 25, and 26 of the instant application are drawn to gene expression libraries comprising mobilizable shuttle vectors linked to multiple cDNA or genomic DNA fragments, and their method of making.

Copending Application No. 08/639255 shows gene expression libraries comprising shuttle vectors linked to multiple cDNA or genomic DNA fragments, and their method of making. Copending Application No. 08/639255 does not show mobilizable shuttle vectors.

Frost et al. reviews mobilizable plasmids that can be introduced into host cells by a process of conjugation.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to modify the libraries of copending Application No. 08/639255 by use of mobilizable shuttle vectors because Frost et al. shows that mobilizable vectors may be used to introduce plasmids to host cells by a process of conjugation.

This provisional rejection might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the copending application was derived from the inventor of this application and is thus not the invention "by another," or by a showing of a date of invention for the instant application prior to the effective U.S. filing date of the copending application under 37 CFR 1.131.

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9. Certain papers related to this application may be submitted to Art Unit 1805 by facsimile transmission. The FAX number is (703) 308-0294. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 CFR 1.6 (d)). NOTE: If applicant *does* submit a paper by FAX, the original copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED, so as to avoid the processing of duplicate papers in the Office.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to John S. Brusca, Ph.D. whose telephone number is (703) 308-4231. The examiner can normally be reached on Monday through Friday from 9 AM to 5 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, George Elliott, Ph.D., can be reached at (703) 308-4003.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

John S. Brusca, Ph.D.

Examiner

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PRIMARY EXAMINER  
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